UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON

IN RE DIGITEK®
PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 27
(Motion to Expand Scope of Discovery)

This Multi-District Litigation concerns claims "related to the marketing, designing, manufacturing, producing, supplying, inadequately inspecting, inadequately testing, selling, and distributing dangerous, defective, misbranded and adulterated Digitek® (Digoxin)," which was manufactured at the Actavis Totowa Little Falls, New Jersey plant. (Master Consolidated Complaint for Individuals, "Master Complaint," docket # 73, at 1.) Pending before the court is Plaintiffs' motion to expand and define the scope of discovery (# 144). Defendants Actavis, Inc., Actavis Elizabeth, LLC, and Actavis Totowa, LLC ("Defendants") have responded in opposition (# 146). Plaintiffs have filed a reply (# 147).

The facts, according to Plaintiffs, are that defendant Actavis Totowa, LLC acquired the Little Falls plan in December, 2005, and manufactured numerous medications, including Digitek®, a generic form of digoxin. (Master Complaint, # 73, ¶ 18, at 5.) In

January, 2006, the Food and Drug Administration ("FDA") conducted an inspection of the Little Falls plant and, in August, 2006, issued a warning letter concerning the reporting and investigating of adverse drug events ("ADE"). Id., ¶¶ 19-23, at 5-6. In July, 2006, FDA inspected the Little Falls plant and, in February, 2007, issued a revised warning letter concerning deviations from current good manufacturing practices, resulting in the adulteration of certain medications manufactured by Actavis Totowa, LLC. Id., ¶¶ 24-37, at 6-9. On April 25, 2008, FDA announced a Class I recall of all lots of Digitek® manufactured and marketed by named defendants "due to the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure." Id., ¶¶ 38, at 9-10. The filing of various civil actions followed the recall, and the cases were designated for handling as multi-district litigation in this District.

Plaintiffs seek to expand the scope of discovery from Digitek® only to include all manufacturing processes of the Actavis Totowa Little Falls, New Jersey facility for all product lines. (Motion, # 144, at 6.) Plaintiffs assert, based on Rule 30(b)(6) depositions and review of documents, that there was extensive commingling of product lines within the Actavis plant and that "[t]here is no way to separate out the Digitek® product line from

that of any of the other 105 product lines manufactured contemporaneously at the Little Falls plant. All equipment and all personnel were interchangeably utilized to manufacture all products." Id.

In support of their motion, Plaintiffs have included excerpts from the depositions of Actavis employees James Fitzpatrick (job title not given) and Arthur Delicato, Site Director Quality Assurance (quality assurance director for New Jersey solid oral dose operations). (# 144, Ex. C, at 29.) Mr. Fitzpatrick testified that "[s]omeone isn't responsible for the production of Digitek. Someone's responsible for the production of all the products." Id., Ex. B, at 137.

Mr. Delicato stated that he began his duties in May, 2008, after the recall at issue in this case. Id., Ex. C at 30. He had no responsibility for Actavis Totowa prior to May of 2008. Id. Mr. Delicato explained that supervisors of manufacturing solid oral dose medications were not limited to a particular drug; "[t]hey would be working on a given product that was scheduled for a given day." Id., at 49.

> Q. On day 1 through day 5, Mr. Patel may be in charge of a production of medication A. And on day 6 to day 10, he may be a supervisor in charge of medication B. And on day 11 through 15, he may be on medication C. Is that right?
>
> A. Yes, to an extent.
>
> Q. Okay.

> A. On a given day, they would be in charge of multiple products.
>
> Q. Okay.
>
> A. So it's not – it could be two products; it could be five products. It's whatever the schedule required and the availability of the equipment.

Id., at 50-51. He stated that supervisors have defined areas of coverage, based on "what they were hired for and their training." Id., at 56. There is no single person and single chain of command for a given product line. Id., at 59.

Exhibit E to Plaintiffs' motion is a "**WARNING LETTER**" dated August 15, 2006, from the Central Region of the Food and Drug Administration, relating to an inspection at the Little Falls plant conducted from January 10 through February 8, 2006, concerning compliance with postmarketing Adverse Drug Experience (ADE) reporting requirements. Id., Ex. E, at 1. The letter states that there were "six potentially serious and unexpected adverse drug events dating back to 1999 for products such as Digoxin . . .." Id., at 2. The letter details other serious deficiencies of Actavis Totowa in maintaining records of ADE and reporting them with respect to unnamed medications. Id., at 2-3.

Exhibit F to Plaintiffs' motion is a "**REVISED WARNING LETTER**" dated February 1, 2007, from the Central Region of the Food and Drug Administration, relating to an inspection at the Little Falls plant conducted from July 10 through August 10, 2007, concerning compliance with current Good Manufacturing Practice (cGMP)

regulations. Id., Ex. F, at 1. The letter states that the inspection

> revealed that drug products manufactured in your facility are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) in that the methods used in, or the facilities or controls used for their manufacture, processing, packing, or holding do not conform with cGMPs, to assure that such drug products meet the requirements of the Act.

Id. Various deficiencies are described; the only specific reference to the drug at issue in this case was as follows:

> 7. Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment is adequately cleaned between the manufacture of different drug products. [21 CFR 211.67(b)] For example:
>
> a) Cleaning validation was performed for the process trains without evaluating for sample recovery for numerous products, including: . . . Digoxin Tablets, USP, 0.25 mg.

Id., at 4. FDA also noted that "[a]lthough according to your firm's procedure, "PRD-011: Blenders - Preventative Maintenance and Repairs," preventative maintenance is to be conducted on [redacted] every six months, no maintenance had been conducted between January 8, and December 8, 2004, or between May 12, 2005, and May 19, 2006." Id., at 6.

Plaintiffs contend that "it is likely that an incident that occurred during the production of one product would be similar or even identical to an incident involving the production of Digitek®." (# 144, at 7-8.) Plaintiffs further argue:

> The same people operating the same machines were producing products that were out of specification - the exact allegation that is central to Plaintiffs' claims in the present litigation. These deviations from manufacturing specifications are clearly relevant to the present case as they will provide insight as to how and why the deviations in the manufacturing of Digitek® occurred.

Id., at 8.

Plaintiffs anticipate Defendants' argument that production of all the records will be unduly burdensome, and contend that a cost-benefits analysis should result in an expansion of the scope of discovery. Id., at 8-9.

Defendants' brief in opposition makes the following points:

A. Under PTO [Pretrial Order] #12, Plaintiffs are not entitled to discovery of manufacturing process information regarding Actavis Totowa's 106 other products because the information is not "reasonably related" to the Digitek® manufacturing process.

   1. The manufacture of Digitek® is a distinct process that involves a unique set of ingredients, specifications, and equipment.

   2. Plaintiffs have not shown that the manufacture of even a single non-Digitek® product is reasonably related to the manufacture of Digitek®.

B. The court should not expand the scope of discovery or modify PTO #12 to include the discovery of the manufacturing processes of the 106 other products because such discovery is neither relevant nor reasonably calculated to lead to the discovery of admissible evidence.

C. Plaintiffs' motion to expand the scope of discovery to include every product at the Little Falls facility would involve tremendous cost, with no benefit to this litigation, and

would substantially delay these proceedings.

(# 146, at 5-13.)

In support of their brief, Defendants have submitted the partial transcript of a case management conference with Judge Harris (Superior Court, Bergen County, New Jersey) (Exhibit A), the affidavit of Richard Dowling, former Director of Manufacturing Operations for Actavis Totowa LLC at the Little Falls facility (Exhibit B), and the affidavit of Alan M. Winchester of Harris Beach PLLC, electronic discovery group (Exhibit C). Mr. Dowling's affidavit states that from October, 2005 through May, 2008, he was responsible for all manufacturing floor operations at the Little Falls facility. Id., Ex. B, ¶ 3, at 1. He provides extensive information concerning the manufacturing process of Digitek®, and avers that the process "involves a unique set of ingredients, specifications, and equipment." Id., ¶ 9, at 2. Most of the affidavit explains the process and how it is different from other medications produced by Actavis Totowa. Id., ¶¶ 10-43, at 2-8. Mr. Winchester's affidavit details the expense of producing documents relating only to Digitek® (approximately $6 million), and the additional cost of producing documents relating to Defendants' other pharmaceutical products made at the Little Falls plant ($13.5 million to $22.5 million, plus the cost of document review by attorneys). Id., Ex. C.

Plaintiffs' reply makes two major points, with subsidiary

contentions:

I. Plaintiffs are entitled to discovery regarding all products produced at the Little Falls Plant because a reasonable relationship exists between the manufacturing practices of Digitek® and the rest of the product lines.
   a. The discovery and testimony to date supports a finding that the manufacturing processes are in fact reasonably related.
   b. Defendants' claim that Digitek® was recalled due to "double thick" tablets is merely a red herring.

II. Expanding discovery of relevant information is proper based on the Federal Rules pertaining to discovery, controlling legal principles, and a favorable cost benefit analysis of the documents sought.
   a. The information requested is relevant under the Federal Rules of Civil Procedure and broadening the scope of discovery is proper because well reasoned case law supports such action.
   b. Broadening the scope of discovery would in fact lead to a cost saving approach, and would not be unduly burdensome.

(# 147, at 3-13.) Plaintiffs have submitted exhibits which relate to the FDA inspection of the Little Falls plant during the period March 18, 2008 through May 20, 2008 (which encompassed the date of the recall of Digitek®). (## 147-2 through 147-9.)

The court begins with Rule 26(b)(1), *Fed. R. Civ. P.*, which reads:

> **(b) Discovery Scope and Limits.**
> **(1) *Scope in General*.** Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense - including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of

> any discoverable matter. For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence. All discovery is subject to the limitations imposed by Rule 26(b)(2)(C).
>
> **(2) *Limitations on Frequency and Extent.***
>
> * * *
>
> (C) *When Required.* On motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that:
>
> (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;
>
> (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or
>
> (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

Rule 26, *Fed. R. Civ. P.* (West, 2009).

To identify Plaintiffs' claims for the purpose of Rule 26(b)(1), the court has considered only the Master Complaint (# 73). It has nineteen claims:

1. Product liability - failure to warn and instruct Plaintiffs

that Digitek® was in a defective condition, was inherently dangerous and unsafe, and created a high risk of bodily injury and serious harm. Id., ¶ 60, at 15. Plaintiffs sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages. Id., ¶ 65, at 16.

2. Product liability - manufacturing defect. The recalled Digitek® was not made in accordance with Defendants' and/or FDA's specifications or performance standards and was defective because the amount of active ingredient (digoxin) was not consistent among tablets and was not consistent with the dose on the label. Id., ¶ 71, at 17. The damages are alleged in ¶ 73, at 17.

3. Product liability - design defect. The recalled Digitek® was defective in design and formulation, contained inconsistent doses, had side effects which outweighed its potential utility, and lacked adequate warnings. Id., ¶ 78, at 18-19. The damages are alleged in ¶ 81, at 20.

4. Negligence. Defendants were negligent in releasing Digitek® with excess levels of active ingredient, failing to test it properly, failing to manufacture it according to FDA standards, failing to warn, etc. Id., ¶ 84, at 20-22. The damages are alleged in ¶ 88, at 22.

5. Negligence *per se*. Defendants violated the Federal Food, Drug and Cosmetic Act, and failed to use current good manufacturing processes. Id., ¶¶ 91-96. The damages are alleged in ¶ 97, at 24.

6. Breach of implied warranty. Defendants breached the implied warranty that Digitek® was safe for the treatment of certain cardiac problems by not insuring that the active ingredient was consistent among tablets and with its labeled dose. Id., ¶¶ 100-102, at 24.

7. Breach of express warranty. Defendants breached their express warranty that Digitek® contained a dose of digoxin that was consistent with the dose on the label and otherwise safe. Id., ¶ 105, at 25. The damages are alleged in ¶ 109, at 25.

8. Negligent misrepresentation. Defendants misrepresented and/or failed to warn Plaintiffs, the medical community and the public about the risks of Digitek®. Id., ¶ 112, at 26.

9. Intentional misrepresentation. Defendants made misrepresentations and actively concealed adverse information concerning defects in Digitek® concerning the dose of the active ingredient. Id., ¶ 121, at 27-28. The damages are alleged in ¶

126, at 28.

10. Fraud. Defendants fraudulently concealed manufacturing problems with Digitek® and its active ingredient, thereby increasing the risk of adverse events, about which it did nothing. Id., ¶ 129, at 29. The damages are alleged in ¶ 136, at 30-31.

11. Constructive fraud. Defendants were in a unique position of knowledge concerning the defects in Digitek®, took unconscionable advantage of their dominant position of knowledge, and thereby engaged in constructive fraud. Id., ¶¶ 138-141, at 31. The damages are alleged in ¶ 143, at 32.

12. Violation of West Virginia Consumer Credit and Protection Act. Defendants violated the statute by making misrepresentations and concealing material facts concerning Digitek®. Id., ¶ 147, at 32. The damages are alleged in ¶ 150, at 33.

13. Violation of applicable consumer protection and/or unfair trade practices statutes. Defendants violated the consumer protection statutes of every state. Id., ¶ 152, at 33-39. The damages are alleged in ¶ 154, at 39.

14. Wrongful death. Defects in Digitek® caused the death of some plaintiffs. Id., ¶ 156, at 40.

15. Survival action. Those plaintiffs who died because of defects in Digitek® suffered injury, pain, disability, etc. plus economic damages. Id., ¶ 161, at 40-41.

16. Medical monitoring. Defendants' actions have put Plaintiffs at a heightened risk of very serious health complications which requires diagnostic medical examinations. Id., ¶ 165, at 41. Defendants should be required to establish a medical monitoring program. Id., ¶ 167, at 41.

17. Unjust enrichment. Defendants made profits and enjoyed benefits from sales of Digitek®, have been unjustly enriched, and should be required to disgorge. Id., ¶¶ 170-173, at 42.

18. Medicare Secondary Payer Act. Defendants should pay "double damages" pursuant to 42 U.S.C. § 1395y(b)(3)(A). Id., ¶ 175, at 43.

19. Loss of consortium. Spouse plaintiffs and/or family member plaintiffs have suffered economic and emotional losses as a result of Defendants' actions causing injuries to Plaintiffs. Id., ¶¶ 177-181, at 43-44. The damages are alleged in ¶ 182, at 44.

The Master Complaint's claims relate only to the medication Digitek®, but its allegations are not limited to the recall of double thick tablets. The court's understanding of the theory of the Master Complaint is as follows: due to failure to comply with current Good Manufacturing Practices and to conduct effective quality assurance in production, some Digitek® tablets manufactured during the period December, 2005 through April 25, 2008, were defective in that their labeled dose of the active ingredient was inconsistent with the actual dose, with the result that some patients suffered adverse drug events or other injury, including death, which were not investigated and reported in a manner consistent with FDA regulations.

According to Richard Dowling's affidavit, Digitek® is manufactured by blending the active ingredient, digoxin, with corn starch and other substances, using three blenders (a V-shape, a portable, and a 50 cubic foot) before a final blend in the 50 cubic foot blender. (# 146, Ex. B, ¶ 27, at 6.) During the period in question, Digitek® was blended in room 117 of the Little Falls plant. Id. It was pressed into tablets in rooms 119 and 120. Id. There was little overlap between the equipment used to make Digitek® and the equipment used to make other medications. Id., ¶ 28, at 6. Mr. Dowling states that no more than 14 other products were blended in room 117, the V-shaped blender was used to make no more than ten other products, the portable blender was used

exclusively to blend Digitek®, and the 50 cubic foot blender was used to blend only one product other than Digitek®. Id., ¶¶ 29-32, at 6.

Mr. Dowling's affidavit states that the tools and dies used for tablet compression of Digitek® are utterly unique. Id., ¶¶ 14-22, at 3-5. Nonetheless, the recall which prompted this litigation was ordered to address double thick tablets.

The FDA warning letters from 2006 and 2007 (# 144, Exs. E and F) constitute evidence that inspectors with knowledge of pharmaceutical manufacturing were not satisfied with Defendants' compliance with applicable federal regulations, current good manufacturing practices, including cleaning and maintenance of manufacturing equipment, and effective quality control. The inspectors noted that digoxin tablets were among the products with inadequate cleaning validation. The FDA identified problems at the Little Falls plant throughout the period which is relevant to this litigation, as demonstrated by the warning letters and the 2008 FDA inspection documents attached to Plaintiffs' reply (# 147). In 2008, FDA observed as follows:

- Drug products failing to meet established specifications and quality control criteria are not rejected. Although Quality Assurance was aware of the "double thick" tablet findings, the batch was then released based on AQL sampling which included visual inspection of [redacted number] tablets. No additional thickness testing or analytical evaluation of the double thick tablets was conducted. No root cause was determined for the defect; however the lot was released to the market by the Quality Unit on 1/28/08 following the visual inspection. There was no documented evaluation of the approximately

[redacted] lots that remained on the market at the time of inspection.

- Determinations of conformance to appropriate written specifications for acceptance are deficient for in-process materials. Although three out of specification results were obtained for blend uniformity at the "Right-Top" same location for Digoxin Tablets 0.125 mg . . ., no manufacturing investigations were conducted. Additional samples were used to retest the blend and were reported. [Two lots were subsequently released; one lot was "not released due to atypical content uniformity results."]
- Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. Although QA investigation 07-093, dated 1/25/08, for double thick Digoxin Tablets 0.125 mg, lot # 70924A1, did not establish a root cause for the defective tablets, the investigation was not expanded to evaluate all finished product lots or strengths of Digoxin Tablets. At the time of inspection there were approximately 89 lots of Digoxin Tablets 0.125 mg and 78 lots of Digoxin Tablets 0.250 mg on the market within expiry.
- Changes to written procedures are not reviewed and approved by the quality control unit. The Quality Unit did not review and approve [redaction] . . . to document the transfer of the [redaction - V-blender] used for the production of Digoxin Tablets, from the Little Falls, NJ manufacturing facility to the Riverview, NJ manufacturing facility. No formal qualification was conducted following the movement of the blender from one sit to another.
- Drug product production and control records are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Investigations of Deviation Reports require a review by Quality Assurance, an approval by Regulatory Affairs/Quality Compliance and an approval of product disposition by the Head of Quality Assurance. On multiple occasions, these three signatories were completed by the same individual. [Example: Deviation Report # 07-093, regarding double thick Digoxin Tablets 0.125 mg, lot # 70924A1.]

(## 147-2 and -3, Exs. 1 and 2.)

After careful review of the FDA materials and other exhibits submitted by the parties, the court is persuaded that Plaintiffs

have shown good cause for a limited expansion of the scope of discovery. For the most part, the exhibits support a conclusion that Digitek® was produced uniquely, with equipment which was not widely used for other products. Of concern is the FDA's observation that "{i]nvestigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy." (# 147-3, Ex. 2, at 12.)

Plaintiffs' contention that an incident involving one product "would be similar or even identical" to an incident involving Digitek® is too speculative to justify the enormous and expensive expansion of discovery they seek.

In order to strike a balance between a too-stringent limitation to Digitek® production only and a too-broad expansion to all product lines, the court finds that Plaintiffs have shown good cause for a modest expansion of the scope of discovery to include records of Little Falls production and the use of equipment for products other than Digitek®, which immediately preceded the use of that equipment for the production of Digitek®. That is, if the 50 cubic foot blender was used to blend a product other than Digitek®, ("product A"), and the blender was next used to blend Digitek® or one of its precursors, then the scope of discovery will include the batch record for product A. If records indicate that a blender was

used for product A and was immediately thereafter used for Digitek®, a fair assumption can be drawn that the blender was not cleaned between uses. If compression and tableting equipment was used for product B immediately before a batch of Digitek®, then the batch record and associated testing data for product B is discoverable, including any indications of equipment malfunctions or the use of inappropriate dies. Assuming that a plaintiff experienced an adverse drug event or other injury associated with digitalis toxicity, and linked that event with the ingestion of Digitek®, it is the court's intention that such plaintiff should be able to trace backwards the lot number of his prescription to the manufacture of those tablets, and to determine the likelihood that the Digitek® contained only the ingredients it was supposed to contain, in the specified amounts. In light of the FDA warning letters, if the court were to refuse to expand discovery to records which reflect the use or misuse and operation or malfunctioning of equipment immediately before each batch of Digitek®, Plaintiffs would be unduly limited in their ability to determine whether a given batch of Digitek® was more likely than not "adulterated" and/or associated with an adverse drug event, other injury or death.

Accordingly, it is hereby **ORDERED** that Plaintiffs' motion to expand the scope of discovery (# 144) is granted with respect to Little Falls product batches the production of which immediately

preceded the production of Digitek® batches, using any of the same equipment, as described above, and otherwise denied. The court **FINDS** that the expanded scope of discovery is "manufacturing information about a product other than Digitek® [which] is reasonably related to Digitek® manufacturing" as that phrase is used in Pretrial Order # 12, Section II.F.4.

The Clerk is directed to file this Order in 2:08-md-1968 which shall apply to each member Digitek®-related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:09-cv—00757. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: July 1, 2009

Mary E. Stanley
Mary E. Stanley
United States Magistrate Judge